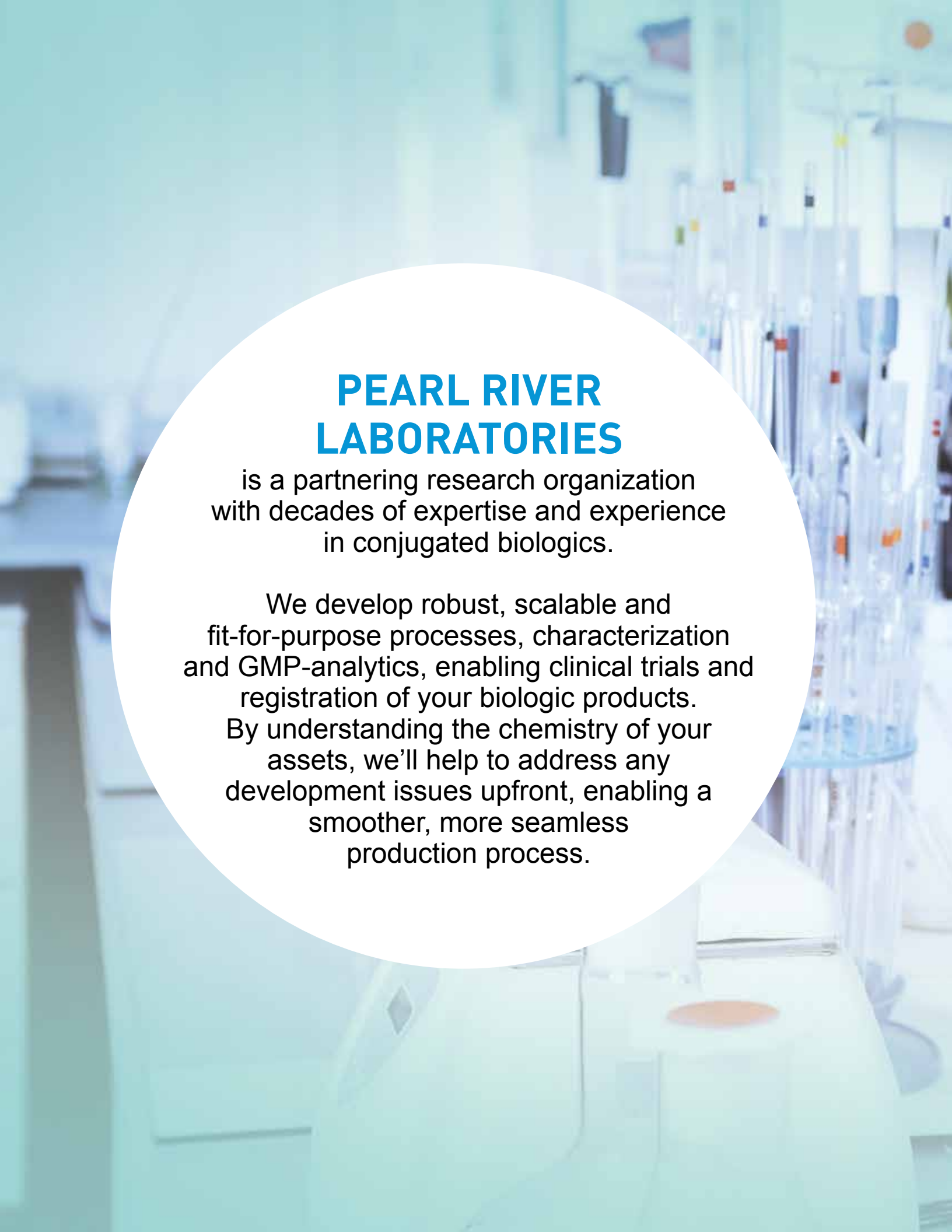
YOUR PARTNER FOR INTEGRATED BIOLOGICS DEVELOPMENT.

Pearl River Laboratories

OUR MISSION:
to embrace the challenges of drug discovery and development by applying our analytical and process development expertise in support of new treatments that will benefit patients.



PEARL RIVER LABORATORIES

is a partnering research organization with decades of expertise and experience in conjugated biologics.

We develop robust, scalable and fit-for-purpose processes, characterization and GMP-analytics, enabling clinical trials and registration of your biologic products. By understanding the chemistry of your assets, we'll help to address any development issues upfront, enabling a smoother, more seamless production process.

GMP ANALYTICAL SERVICES

Pearl River Laboratories provides a wide range of phase appropriate analytical services to the pharmaceutical and biopharmaceutical industry. We are a fully compliant 21CFR part11 laboratory meeting your cGMP analytical testing needs from Phase1 through commercial. PRL takes pride in meeting customers needs through high quality, customer focus, flexibility and innovation.

GENERAL ASSAYS

- Appearance (Coloration)
- Appearance (Clarity)
- Appearance (visible particulates)
- Protein concentration (UV)
- pH
- Density Determination

CHROMATOGRAPHY-BASED ASSAYS

- Aggregation by SEC
- Distribution by HIC
- Drug Conjugate ratio by UV, HIC, RP
- Free drug & related species by RP-HPLC
- CEX
- Peptide mapping profile
- Glycan Fingerprinting
- Methionine oxidation

CHARGE-BASED ASSAYS

- cGE (reduced, Beckman-Coulter 800 Plus)
- cGE (non-reduced, Beckman-Coulter 800 Plus)
- Charge Isoforms (iCE)

COLORIMETRIC ASSAYS

- MBTH
- Anthrone

OTHER ASSAYS

- Endotoxin
- Moisture content

HEIGHTENED CHARACTERIZATION ASSAYS

- Peptide mapping
- Glycan Fingerprinting
- Methionine oxidation
- Degradant characterization
- Forced Degradation studies
- NMR (1D, 2D, etc.)
- LC-MS-MS, MALDI for large molecules

COMPENDIAL TESTING

- USP/NF
- EP
- JP
- ACS

IMPURITIES ISOLATION, IDENTIFICATION AND CHARACTERIZATION

METHOD DEVELOPMENT, QUALIFICATION AND VALIDATION

- HPLC assays, including stability-indicating assays
- Charge-based assays (cGE, iCE)
- Chiral HPLC assays
- GC-FID methods for residual solvents
- GC-MS, LC-MS methods for potential genotoxic impurities (PGI's)
- Counter Ion methods by titration & HPLC
- Customizable assays
- Specialized assays

EXTRACTABLES AND LEACHABLES

- Development of Extractables and Leachables (E&L) methods (Volatile, Semi-Volatile and Non-Volatile)
- Risk Assessment studies for equipment, containers and closures
- Assess for (E &L) using established protocol studies for Biologics and Medical Devices undergoing Stability evaluation

DISCOVERY AND PROCESS DEVELOPMENT OF CONJUGATED BIOLOGICS

Pearl River Laboratories (PRL) provides a wide range of bioconjugation services from Discovery through Process Development and Technical Transfer to a CMO for bioconjugates including ADCs, Vaccine conjugates, Peptide Conjugates, Oligonucleotide conjugates, etc.

DISCOVERY

- Conventional (Cys, Lys, etc.) & Site-specific (Cys mutant, unnatural amino acids, enzyme-based, etc.) conjugations for ADCs
- Conjugation of polysaccharides
- Conjugation of Oligonucleotides
- Purification using SEC, HIC, IEX, Mixed mode, etc.
- Purification/buffer exchange using TFF
- Full Characterization

TRANSFER TO CMO:

- Provide detailed technical transfer protocol
- GLP batch record provided
- Oversee demo runs

GLP TOXICOLOGY

- Optimization of conjugation & purification processes for desired attributes utilizing DOE models
- Preparation of GLP tox material
- Full Characterization & Release
- Comprehensive report

COORDINATE GMP MANUFACTURE AT CMO

- Batch record review
- Person in Plant to oversee production
- Address issues that arise
- Provide regulatory strategy and guidance

Pearl River Laboratories
401 N. Middletown Rd., Building 205, 2nd floor
Pearl River, NY 10965

845.300.1608 845.735.9400
amar.prashad@pearlriverlabs.com

pearlriverlabs.com